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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,829	12/15/1999	ROBERT-JAN ENZERINK	265280-64723	4338

24395 7590 08/02/2004

WILMER CUTLER PICKERING HALE AND DORR LLP
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WASHINGTON, DC 20004

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

32

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,35,36,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,35,36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/04 has been entered.

Response to Amendment

The reply filed on 1/28/04 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): status of claims is wrong. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant should correct their papers to include the correct status of the claims. Please note that claims 7-15,37, were canceled in the amendment filed 7/15/02 or Paper No. 16 and thus these claims are not withdrawn but are canceled. Also note that claims 16-34 are canceled. These claims were canceled in an amendment filed on 1/16/01 or Paper No. 4 and are not withdrawn, but canceled.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 35, 36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire (5562669) in view of Dumican et al. (4987665) and Roger et al. (6235057). McGuire discloses that allografts can be used as replacement ligaments, col. 6, lines 32-42. McGuire discloses to have sutures attached at a proximal end and distal end and include using semitendinosis and gracilis tendons, col. 5, lines 1-11 and col. 6, lines 60-61. McGuire also discloses the sutures are attached **prior to** implantation to aid in insertion, col. 5, lines 54-62. McGuire additionally discloses preserving grafts that are used for future ligament replacement procedures, col. 6, lines 34-36. It is inherent the preserved graft would be sterilized and packaged. The graft can be a bundle of strands, col. 6, lines 60-61. McGuire additionally discloses that fixation devices are used in "kits" for ligament repair, col. 5, lines 17-22. Because the individual components of applicant's claimed kit *for ligaments* are known in the prior art, it can be construed that any type of combination of these components available at the same time form a "kit". However, McGuire does not disclose a package or kit with sutures attached to the graft (lacking bone plugs) prior to sterilizing and packaging. Dumican teach grafts are packaged and sterilized with pre-attached sutures, col. 11, lines 34-41. Roger et al. teach that bone blocks are not necessary with grafts made from tendons with sutures at the ends, col. 2, lines 28-31. It would have been obvious to one of ordinary skill in the art to have the pre-attached sutures on the graft ligament of

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McGuire and have the sutures already attached prior to packaging and sterilizing as taught by Dumican and not use a bone block as taught by Roger in order to save valuable time for the patient and reduce the surgery time required for placing the sutures in the ligament during the surgery. Also, it would be an advantage to attach the sutures and graft together prior to packaging, in that it reduces extra packaging if they were separate. The elimination of the bone block would reduce the size of the hole required to be bored in the patient's bone.

Claims 5, 6, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Dumican '665 and Roger et al. '057 and further in view of Schmieding '561. McGuire as modified by Dumican and Roger is explained supra. However, McGuire in view of Dumican and Roger do not disclose the use of long strand sutures and various lengths of ligaments. Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire as modified by Dumican and Roger in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

Claims 1-4, 35, 36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Li et al. (5715942) and Roger et al. '057. McGuire is explained supra. However, McGuire does not disclose pre-attached sutures with the graft (lacking bone plugs) in sterile packaging. Li et al. teach of a medical

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device used in surgery that has the sutures pre-attached to the device and provided in sterile packaging, see abstract. Roger et al. is explained supra. It would have been obvious to one of ordinary skill in the art to move the step of pre-attaching the sutures to the graft prior to packaging as taught by Li et al. instead of just pre-attaching the sutures to the McGuire graft and not use bone plugs as taught by Roger prior to implanting such that the graft is ready to be implanted immediately once opened from the package. The elimination of the bone block would reduce the size of the hole required to be bored in the patient's bone.

Claims 5, 6, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Li et al. '942 and Roger et al. '057 and further in view of Schmieding '561. McGuire as modified by Li et al. and Roger et al. is explained supra. However, McGuire in view of Li and Roger do not disclose the use of long strand sutures and various lengths of ligaments. Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire as modified by Li and Roger in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

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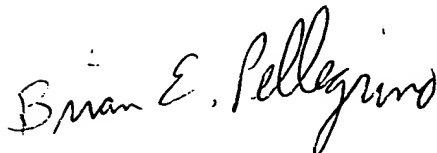
Response to Arguments

Applicant's arguments with respect to claims 1 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.

Brian E. Pellegrino
TC 3700, AU 3738